Oral Argument Not Yet Scheduled

NO. 24-1151

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS INTERNATIONAL UNION, AFL-CIO,

***Petitioner*,**

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,

***Respondent*.**

CONSOLIDATED WITH CASES
NOS. 24-1182, 24-1185, 24-1202, No. 24-1237

OPENING BRIEF OF PETITIONERS UNITED STEELWORKERS, INTERNATIONAL ASSOCIATION OF MACHINISTS AND WORKSAFE, INC.

Randy S. Rabinowitz
Victoria L. Bor
Occupational Safety and Health Law Project, LLC
P.O. Box 3769
Washington, D.C. 20027

CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Parties:

The following entities are parties to these consolidated cases:

Labor Petitioners:

United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO (No. 24-1151)

International Association of Machinists and Aerospace Workers, AFL-CIO (No. 24-1182)

Worksafe, Inc. (No. 24-1202)

Industry Petitioners

Texas Chemistry Council (No. 24-1185)

American Chemistry Council (No. 24-1185)

American Fuel & Petrochemical Manufacturers (No. 24-1237)

American Petroleum Institute (No. 24-1237)

Respondents

Environmental Protection Agency

Michael Regan, Administrator

Intervenor for Industry Petitioners

Olin Corporation

Intervenors for Respondent

Alaska Community Action on Toxics

Sierra Club

Ruling under Review:

These petitions challenge the Environmental Protection Agency's "Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA)," published in the Federal Register on May 3, 2024, at 89 Fed. Reg. 37029. The provision challenged by the Labor Petitioners – codified at 40 C.F.R. § 702.39(f)(2) – is stated in full in the body of this Brief.

Related Cases:

Four separate petitions for review were filed challenging this EPA regulation. Pursuant to 28 U.S.C § 2112, this Court was selected to hear all pending challenges to the regulation. All petitions challenging the rule, including a fifth, subsequently filed petition, have been docketed in this Court and consolidated with the lead case, No. 24-1151. The Petitioners and the case numbers for each petition are indicated in the section of this document titled "Parties."

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

TABLE OF AUTHORITIES (cont.)

Statutes

TABLE OF AUTHORITIES (cont.)

Public Laws

Legislative Materials

Regulations

TABLE OF AUTHORITIES (cont.)

Federal Register

TABLE OF AUTHORITIES (cont.)

Miscellaneous

GLOSSARY

ACGIH	American College of Government Industrial Hygienists
AFP	Assigned protection factor
EPA	Environmental Protection Agency
IAM	International Association of Machinists and Aerospace Workers, AFL-CIO
NIOSH	National Institute of Occupational Safety and Health
NPRM	Notice of Proposed Rulemaking
OSH Act	Occupational Safety and Health Act
OSHA	Occupational Safety and Health Administration
PEL	Permissible exposure limit
PPE	Personal protective equipment
REL	Recommended Exposure Limit
TLV	Threshold Limit Value
TSCA	Toxic Substances Control Act
USW	United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO

INTRODUCTION

These petitions challenge the authority of the Environmental Protection Agency ("EPA"), under the Toxic Substances Control Act ("TSCA"), to consider the use of respirators and other personal protective equipment ("PPE") when evaluating the risk a chemical substance poses to workers. EPA has promulgated a rule that bars the Agency from *assuming* workers are protected by PPE when conducting risk evaluations but gives the Agency unlimited discretion to consider PPE when it has "reasonably available information" on its use. 40 C.F.R. § 702.39(f)(2). This approach—which conflates and confuses risk evaluation with risk management—is barred by TSCA.

Petitioners United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO ("USW"), International Association of Machinists and Aerospace Workers, AFL-CIO ("IAM"), and Worksafe (collectively, "Labor Petitioners") submit that TSCA prohibits EPA from considering any PPE use when assessing risk for three reasons: (1) TSCA's plain language prohibits EPA from considering "nonrisk" factors, such as exposure control methods, when conducting risk evaluations, 15 U.S.C. §§ 2605(b)(4)(A) and (F); (2) doing so is inconsistent with the "best available science," *id.* § 2625(h); and (3) the Agency's rationale for considering PPE use rests on fundamental misunderstandings about the requirements of the Occupational Safety and Health

Act ("OSH Act")—and both the Occupational Safety and Health Administration ("OSHA") and the National Institute of Occupational Safety and Health ("NIOSH") have told EPA as much. While, under appropriate circumstances, EPA may consider respirator and PPE use, as well as other feasible exposure controls, when developing risk *management* rules to eliminate unreasonable risk, any consideration of PPE at the risk *evaluation* stage—the goal of which is exclusively to determine whether such a risk exists—would violate TSCA.

STATEMENT OF JURISDICTION

EPA adopted the rule, "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)," 89 Fed. Reg. 37028 (May 3, 2024) ("Revised Framework Rule"), pursuant to TSCA section 6(b)(4), 15 U.S.C. § 2605(b)(4). TSCA section 19(a), *id.* § 2618(a)(1)(A), authorizes "any person" to petition for review of "a rule . . . promulgated under this subchapter" and authorizes review in the District of Columbia Circuit or the circuit in which a party has its principal place of business. USW filed a timely petition for review in this Court on May 21, 2024. IAM, Worksafe and other parties filed petitions in various other circuit courts. The Joint Panel on Multidistrict Litigation selected this Court to hear all challenges to EPA's rule pursuant to 28 U.S.C. § 2112(a)(3).

STATEMENT OF THE ISSUES

I. Whether the provision in EPA's Revised Framework Rule, 40 C.F.R. § 702.39(f)(2), which permits the Agency to consider the use of personal protective equipment in performing risk evaluations, violates section 6(b)(4)(A) of the Toxic Substances Control Act, 15 U.S.C. § 2605(b)(4)(A), which prohibits the agency from considering "nonrisk" factors during risk evaluation.

II. Whether consideration of respirator use and other personal protective equipment in risk evaluation is inconsistent with TSCA's mandate that EPA rely on the "best available science."

III. Whether Section 702.39(f)(2) of EPA's Revised Framework Rule is arbitrary because it rests on a fundamental misunderstanding of the requirements of OSHA standards.

STATEMENT OF THE CASE

TSCA required EPA to "establish, by rule, a process to conduct risk evaluations" within one year after Congress adopted the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016). 15 U.S.C. § 2605(b)(4)(B). EPA complied with this mandate by publishing rules to establish a framework for risk evaluations in 2017. *See* EPA, "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act," 82

Fed. Reg. 33726 (July 20, 2017) ("2017 Framework Rule"). The Ninth Circuit reviewed those rules in *Safer Chemicals, Healthy Families v. EPA,* 943 F.3d 397 (9th Cir. 2019) (upholding the rules in part, vacating the rules in part, and declining to address other issues as not ripe). The instant petitions challenge a provision of the Revised Framework Rule that EPA adopted when it revised the 2017 Framework Rule in 2024.

I. Relevant Statutory Provisions

Congress enacted TSCA in 1976 to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. REP. NO. 94-698 at 1, *as reprinted in* 1976 U.S.C.C.A.N. 4491 (Mar. 16, 1976). Congress recognized that "[w]hile individual agencies may be authorized to regulate occupational, environmental, or direct consumer hazards," none "ha[d] the authority to look comprehensively at the hazards associated with the chemical," as opposed to those hazards within each agency's narrower jurisdiction. *Id*. at 2. The Act gave EPA "the authority to look at the hazards in total." *Id*.

As originally enacted, TSCA limited EPA to using the "least burdensome requirements" to regulate chemicals. *See Corrosion Proof Fittings v. EPA,* 947 F.2d 1201, 1229–30 (5th Cir. 1991) (remanding EPA's asbestos ban for failure to consider

least burdensome alternative). As a result of this high bar, EPA regulated relatively few chemicals under the Act.

In 2016, Congress—noting that TSCA's effective implementation "ha[d] been challenged by shortcomings in the statute itself, and by several key decisions of Federal Courts"—amended TSCA to "provide EPA the authority necessary for efficient and effective regulation of chemical risks." S. REP. NO. 114-67, at 2 (2015).[1] To accomplish this goal, Congress largely rewrote section 6 of TSCA, the provision that governs review and regulation of existing chemicals. As amended, TSCA requires the Agency to follow a two-step process for evaluating and managing the health and environmental risks posed by a toxic substance, and to do so under a strict schedule.

First, section 6(b)(4) directs EPA to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, *without consideration of costs or other nonrisk factors,* including an unreasonable risk to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2605(b)(4)(A) (emphasis added).[2] TSCA specifically identifies workers as such a

[1] The Senate report is in the Administrative Record as Docket EPA-HQ-OPPT-2023-0496-0420. Documents in the Administrative Record will hereinafter be referred to as "AR Ex. ___," using the last four digits of the docket number (*e.g.,* for the Senate report, "AR Ex. 0420").

[2] The full text of relevant portions of TSCA are set forth in the Statutory Addendum to this brief.

subpopulation. *Id.* § 2602(12). Congress required EPA to develop procedures, by rule, to govern such risk evaluations. *Id.* § 2605(b)(4)(B).

Second, "[i]f [EPA] determines [in a risk evaluation] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of those activities, presents an unreasonable risk of injury to health or the environment," TSCA directs EPA to enact regulations "to the extent necessary so that the chemical substance or mixture no longer presents such risk." *Id.* § 2605(a). As amended, TSCA no longer requires EPA to use the "least burdensome" means of managing risk, a requirement lawmakers said had "paralyzed EPA and prevented [it] from regulating some extremely toxic chemicals." 162 Cong. Rec. 7498 (2016) (statement of Sen. Markey); *see also* 162 Cong. Rec. 7984 (2016) (explaining that, by "delet[ing] the paralyzing 'least burdensome' requirement and instruct[ing] that EPA's rule must ensure that the chemical substance or mixture 'no longer presents' the unreasonable risk identified in the risk evaluation," the Amended Act "clearly rejects the regulatory approach and framework that lead to the failed asbestos ban and phase-out rule of 1989"). Instead, Congress directed EPA, when adopting a risk management rule, to "consider" several enumerated factors, including "the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions" and "the cost effectiveness of the proposed regulatory action." *Id.* § 2605(c)(2)(A)(iv)(II)–(III).

Through this two-step process, Congress intended to "'de-couple[]' [EPA's] science-based risk decision about a chemical's safety under its intended conditions of use from [EPA's] decision on how to manage unreasonable risks where chemicals do not meet the safety standard under intended conditions of use." S. REP. NO. 114-67, AR Ex. 0420 at 17. In other words, in evaluating risk, EPA "must determine that a chemical meets the safety standard, or not, based solely on risk to human health and the environment—the integration of hazard and exposure information about a chemical—and not on the basis of other factors such as consideration of the costs or benefits of the substance or of possible restrictions on the substance." *Id*.[3]

II. The Framework Rules

EPA's initial Framework Rule, published in 2017, did not address whether, and if so how, the Agency would consider the use of respirators and other PPE in gauging exposure, and hence, risk to workers. But in conducting the first ten risk evaluations mandated by the amended TSCA, *see* 15 U.S.C. § 2605(b)(2)(A), EPA "assumed that workers were provided and always used personal protective equipment (PPE) in a manner that achieves the stated assigned protection factor

[3] "Safety standard" as used in the Senate bill refers to the same requirements that appear in the enacted section 6(b)(4). *See* S. REP. No. 114-67, AR Ex. 0420 at 17 (the "Safety Standard" "ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use.")

(APF) for respiratory protection . . . .” 89 Fed. Reg. at 37037. Relying on this assumption, EPA divided the exposure measurements available to it by the assigned protection factor for the respirators EPA assumed workers would be wearing.[4] As a result, in determining the level of risk for most of the initial 10 chemicals it evaluated, EPA relied on exposure assumptions that were a fraction of the actual measured workplace exposures.

Unions and other commenters objected strenuously to EPA’s unprecedented assumption of widespread respirator and other PPE use in gauging occupational exposures. Both NIOSH and OSHA objected to EPA’s discounting of occupational exposure based on presumed respirator use.[5] The agencies—the Federal Government’s lead organizations on controlling workplace hazards—gave three reasons for objecting to EPA factoring PPE use into its risk assessment. First, attempting to adjust exposure data according to some assumed assigned protection

[4] For example, if the eight-hour time weighted average exposure of a worker to chemical X is 100 parts per million (ppm), and the employer required the worker to wear a half-mask respirator with an APF of 10, EPA would assume the worker’s exposure was 10 ppm, not 100 ppm.

[5] NIOSH and OSHA commented to EPA as part of the inter-agency review process. The American Federation of Labor and Congress of Industrial Organizations (“AFL-CIO”) obtained copies of each agency’s comments to EPA on the Agency’s draft risk evaluations of methylene chloride, 1,4-dioxane, and cyclic aliphatic bromide cluster (HBCD), and placed these comments in EPA’s record on the Revised Framework Rule. *See* AR Ex. 215 Atts. 1-6.

factor was simply bad science, as "APFs are intended to guide the selection of an appropriate class of respirators to protect workers *after* a substance has been determined to be hazardous, *after* an occupational exposure limit is established, and only *after* feasible engineering, work practice, and administrative controls have been put in place."[6]

Second, the agencies pointed out that the assumption that all workers would be provided with respirators or wear them correctly was simply unwarranted. OSHA explained that it "does not evaluate respirator impact in an initial characterization of risk since [doing so] presumes all workers in an occupational application group will be properly trained, fitted, and wear respirators, which is rarely the case."[7] In commenting on EPA's methylene chloride risk evaluation, NIOSH agreed, calling the assumption that all workers would be wearing PPE an "assumption [that] severely underestimates worker exposure,"[8] and noting that "it is NOT plausible to assume that every worker would be in a respirator . . . . This is an incorrect

[6] OSHA Comments on EPA's Methylene Chloride Risk Evaluation ("OSHA Methylene Chloride Comments"), AR Ex. 0215 Att. 6 at 1, 6 (emphasis in original).

[7] *Id.* at 6.

[8] NIOSH Comments on EPA's Methylene Chloride Risk Evaluation ("NIOSH Methylene Chloride Comments"), AR Ex. 0215 Att. 5 at 4.

assumption and should not be used in risk estimation nor in developing findings of unreasonable risk."[9]

Finally, the agencies argued that EPA's focus on PPE use was inconsistent with the hierarchy of controls, which NIOSH characterized as "a long-standing industrial hygiene best practice" that prioritizes chemical elimination, substitution, engineering controls, and administrative controls—measures that eliminate or reduce the actual presence of a hazard—and prohibits employers from using PPE until they have exhausted those preferred options.[10] OSHA agreed, pointing out that

> [d]irect adjustment of exposure estimates using APFs . . . ignores the hierarchy of controls in which respirator use is a last resort after engineering controls and other workplace practices. APFs and respirator use is better addressed during risk management after unreasonable risk in the absence of respirator use has been determined.[11]

EPA subsequently acknowledged that its practice of reducing exposure measurements by the APF assigned to a respirator that EPA assumed workers were wearing "could result in risk evaluations that underestimate risks, and in turn,

---

[9] *Id.* at 3 (emphasis in original).

[10] *Id.* at 4. *See also* OSHA, "Final Rule: Occupational Exposure to Methylene Chloride," 62 Fed. Reg. 1495, 1582 (Jan. 10, 1997) (describing hierarchy of controls) ("OSHA Methylene Chloride Rule").

[11] OSHA Methylene Chloride Comments, AR Ex. 0215 Att. 6 at 6.

prevent risk management rules from affording necessary protections." EPA, Notice of Proposed Rulemaking ("NPRM"), "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)," 88 Fed. Reg. 74292, 74294 (Oct. 30, 2023) ("Framework Rule NPRM"); Revised Framework Rule, 89 Fed. Reg. at 37037. In fact, when the Agency revised its risk determinations for several chemical substances to eliminate the assumption that all workers wore respirators all the time, it found that a number of additional conditions of use contributed to the unreasonable risk posed by the chemical.[12]

---

[12] For example, in its 2020 Risk Evaluation for Methylene Chloride, in which the Agency had assumed all workers were protected by PPE, EPA found that workers in six occupational conditions of use were not exposed to unreasonable risk. When EPA eliminated the assumption of universal PPE use, the Agency found that workers in *all* occupational conditions of use faced unreasonable risk. *See* EPA, "Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability," 87 Fed. Reg. 67901, 67905–06 (Nov. 10, 2022). In addition, while in its 2020 Risk Evaluation for Trichloroethylene, EPA initially found that most occupational conditions of use posed unreasonable risk, when the Agency eliminated the assumption of universal PPE use, it determined employees faced significantly higher risks. EPA, "Trichloroethylene (TCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability," 88 Fed. Reg. 1222, 1226 (Jan 9, 2023). *See also,* EPA, "Cyclic Aliphatic Bromide Cluster (HBCD); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability," 87 Fed. Reg. 38747, 38751 (June 29, 2022) (by eliminating the assumption of PPE use, EPA finds more conditions of use contribute to unreasonable risk).

To codify its new policy, EPA adopted the Revised Framework Rule, which details whether, and if so how, it will consider PPE use during risk evaluation. EPA's Revised Framework Rule provides:

> In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination.

40 C.F.R. § 702.39(f)(2).

In the preamble to the rule, EPA explained that it "distinguishes 'assumed use' of PPE from use that is supported by the reasonably available information and therefore known to be inherent in the performance of an activity." Revised Framework Rule, 89 Fed. Reg. at 37037. EPA gave no examples of when PPE use might be "inherent" in performing an activity. EPA further explained that "where stakeholders have information that demonstrates effective occupational exposure control practices" such as "the standards of a particular industry," EPA will use that information "to inform both the risk evaluation and risk management processes." *Id.* at 37038. EPA emphasized that it intends to consider "occupational exposure control practices as part of the risk evaluation." *Id.*; *see also* 40 C.F.R. § 702.39(d)(3) (information evaluated as part of the exposure assessment may include "occupational exposure control measures").

SUMMARY OF THE ARGUMENT

TSCA requires EPA to make risk determinations without regard to PPE. Labor Petitioners fully support EPA's decision not to *assume* the use of PPE in making a risk determination. But neither may EPA consider PPE use when it has "reasonably available information" on PPE.

Respirators, together with engineering controls, work practices, and other PPE are means of *managing* hazardous exposures; in TSCA parlance, they are "nonrisk factors" that the statute prohibits EPA from considering when conducting risk evaluations and making risk determinations. 15 U.S.C. § 2605(b)(4)(A). Furthermore, accepted industrial hygiene practice, as well as OSHA regulations, require that worker exposures be measured, and risk determined, without regard to respirators. Consideration of PPE use in assessing risk is unprecedented and at odds with TSCA's requirement that EPA rely on the "best available science." *Id.* § 2625(h).

What is more, the actual impact of respirator use cannot be effectively measured because a sampling device cannot be placed inside a respirator without breaking the face seal. Any policy that *permits* EPA to take this kind of "occupational exposure control measure" into account when assessing risk would lead to risk determinations lacking in scientific support. Both OSHA and NIOSH have technical expertise on issues of occupational risk assessment and control; both

agencies have told EPA that it is wrong to take respirator use into account when assessing risk. PPE should be considered, if at all, during risk management as a possible exposure control measure in combination with other control measures. To the extent that the first sentence of 40 C.F.R. § 702.39(f) gives EPA discretion to consider PPE use when it has some undefined amount of "readily available information," that portion of the Framework rule violates TSCA, and this Court should declare it to be invalid.[13]

STANDING

USW and IAM have organizational standing to bring these petitions. This Court has recognized that "[a]n organization has standing to sue on behalf of its members when . . . its members would otherwise have standing to sue in their own right." *Air Alliance Houston v. EPA,* 906 F.3d 1049,1058 (D.C. Cir. 2018) (citations omitted). To meet the standard for organizational standing, the unions "must demonstrate that at least one of their members would otherwise have standing to sue in his or her own right; that the interests they seek to protect are germane to their

[13] Labor Petitioners raise a facial challenge to EPA's rule because it permits the Agency to consider PPE use during risk evaluation when the statute forbids the Agency from doing so. Labor Petitioners also question what type of evidence EPA would consider to be enough to justify taking PPE use, or the failure of such use, into account. Since EPA has not applied the policy yet and may not do so in the way Labor Petitioners fear, we have not raised any "as applied" challenges believing that they would not be ripe. *See Safer Chemicals,* 943 F.3d at 413 (finding certain "as applied" claims not ripe because it was not clear EPA would conduct its risk assessments in manner Petitioners feared).

organizations' purposes; and that neither the claim asserted nor the relief requested requires the participation of individual members." *Id.* (citing *Sierra Club v. EPA*, 755 F.3d 968, 973 (D.C. Cir. 2014)). USW and IAM satisfy those requirements.

In amending TSCA, Congress directed EPA "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health . . . , including an unreasonable risk to a potentially exposed or susceptible subpopulation," and if the Agency determined there was such an unreasonable risk, to issue regulations so that the chemical "no longer presents such risk." 15 U.S.C. §§ 2605(a) and (b)(4)(A). Congress specifically identified workers as among the subpopulations whose risks EPA was to evaluate and eliminate. *Id.* § 2602(12).

USW represents thousands of workers in the chemical manufacturing industry who are exposed to chemicals EPA has evaluated, is currently evaluating, and will evaluate in the future under TSCA. Indeed, USW is the largest union representing workers in the chemical manufacturing industry. The Ninth Circuit recognized that USW had standing to challenge EPA's initial Framework Rule in *Safer Chemicals, Healthy Families v. EPA,* 943 F.3d at 421. IAM similarly represents workers in various industries, including manufacturing and the aerospace industry, where they are routinely exposed to toxic chemicals. USW and IAM have standing here too because when EPA has taken respirators into account during risk evaluation, the Agency has in several instances decided that members of these unions did not face

unreasonable risks under certain conditions of use.[14] As a result, members of both Unions face the prospect of remaining exposed to chemicals that may harm their health, contrary to TSCA's intent. These members therefore clearly have standing to bring this suit in their own right.

Moreover, a principal objective of both USW and IAM, as the collective bargaining agents of these members over their terms and conditions of employment, 29 U.S.C. § 152(5) (defining "labor organization" as an "organization . . . in which employees participate and which exists for the purpose . . . of dealing with employers concerning . . . conditions of work"), is to ensure that their members work safely, in environments that will not adversely affect their health. Ensuring that EPA properly carries out its obligations under TSCA to identify and eliminate unreasonable risks in the workplace is undoubtedly germane to the Unions' purpose. And finally, pursuing these claims does not require the individual participation of the Unions' members.

[14] For example, in its 2020 risk evaluation for methylene chloride, EPA found that manufacture of the chemical did not pose an unreasonable risk. USW represents workers who manufacture methylene chloride and who would not have been protected by any subsequent methylene chloride risk management rule had EPA not revised its risk evaluation. IAM represents aerospace workers who are also routinely exposed to methylene chloride. Once EPA revised its risk determination by eliminating the assumption of PPE use, members of these Unions gained protections. *See* n. 12, *supra*.

Accordingly, USW and IAM have associational standing to pursue this case. *See Air Alliance Houston,* 906 F.3d at 1058–59 (finding USW had standing to challenge EPA regulation based on its members' exposure). And since USW and IAM have standing, Worksafe may participate as well. *Id.* ("When more than one association brings suit, 'we need only find one party with standing' to satisfy the [standing] requirement" (quoting *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 182 (D.C. Cir. 2017)); *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania,* 140 S. Ct. 2367, 2379 n.6 (2020) ("[A]t least one party must demonstrate Article III standing for each claim for relief").

STANDARD OF REVIEW

Labor Petitioners raise an issue of statutory interpretation; this Court must review an issue of statutory interpretation *de novo* to determine the "best" reading of the term "nonrisk factors" in TSCA section 6(b)(4)(A) and (F), 15 U.S.C. § 2605(b)(4)(A) and (F). *See U.S. Sugar Corp. v. EPA,* 113 F.4th 984, 993–94 (D.C. Cir. 2024) (citing *Loper Bright Enters. v. Raimondo,* 144 S. Ct. 2244, 2261 & n.4, 2273 (2024)).

Labor Petitioners also raise issues of whether the challenged provision of EPA's Revised Framework Rule is consistent with TSCA's mandates. TSCA section 19 provides that the Administrative Procedure Act ("APA")'s scope of review provisions, 5 U.S.C. § 706, do not apply to rules published under 15 U.S.C.

§ 2605(b)(4) such as the Revised Framework Rule at issue here. Instead, "the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i)(I). The APA otherwise requires the Court to set aside agency action that is in excess of an agency's statutory authority, promulgated without "observance of procedure required by law," or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2).

ARGUMENT

I. TSCA Prohibits EPA from Considering PPE in Risk Evaluation.

Any consideration of PPE use during risk evaluation runs counter to Congress's deliberate separation of the risk evaluation process from the risk management process. TSCA section 6(b) directs EPA to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . ." 15 U.S.C. § 2605(b)(4)(A). TSCA requires EPA, in determining whether a chemical presents an unreasonable risk, to "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical." *Id.* § 2605(b)(4)(F). But TSCA directs EPA *not* to "consider costs or other nonrisk factors" in making that risk determination. *Id.* Only after completing a risk evaluation and determining that a chemical presents an unreasonable risk may EPA look to nonrisk factors in

assessing its options for managing that risk pursuant to sections 6(a) and 6(c). *Id.* §§ 2605(a), (c).

Congress separated risk management from risk evaluation to ensure that the agency determines whether a chemical poses unreasonable risk based only on health and environmental effects—that is, to "de-couple[]" the Agency's step-one risk determination from its step-two "decision on how to manage unreasonable risks . . . ." S. REP. NO. 114-67, AR Ex. 0420 at 17. Congress made clear the factors it intended EPA to consider in making its risk determination and the "nonrisk" factors it intended to preclude: Congress intended EPA's risk determination to be a "science-based risk decision" based on "the integration of hazard and exposure information about a chemical." But "costs and other factors such as technical feasibility" or "possible restrictions on the substance" were "to play no part in EPA's safety determinations." *Id.* In the context of the overall scheme of section 6—and Congress' deliberate decision to "de-couple" risk evaluation from risk management—it is clear that TSCA prohibits EPA from considering the effect of control measures, such as respirators or PPE, when determining whether a substance poses an unreasonable risk. *See U.S. Sugar Corp.,* 113 F.4th at 993–94 (Court looks to statutory context to determine the meaning of the Clean Air Act).

Moreover, Congress did "not intend for the implementation of TSCA to conflict with or disregard Occupational Safety & Health Administration's hierarchy

of controls." H.R. REP. NO. 114-176 at 28–29 (2015). This legislative history clarifies Congress' intent: Whatever else the phrase "nonrisk factors" means, it clearly does not permit EPA to consider the effect of PPE—a practice both OSHA and NIOSH describe as inconsistent with the hierarchy of controls—in risk evaluation.

Despite this clear statutory mandate, EPA's prior assumption of widespread PPE use—a "nonrisk factor" under the statute—impermissibly conflated risk evaluation with risk management. As a result, the Agency underestimated the risk toxic substances posed to workers. Revised Framework Rule, 89 Fed. Reg. at 37037.[15] Given that TSCA requires EPA to eliminate the "unreasonable risks" a chemical poses, any analysis that underestimates the risk to workers would undoubtedly affect the risk management approach EPA chooses. In fact, because the statute directs EPA to take regulatory action only when it finds unreasonable risk, where these assumptions lead EPA to conclude that no unreasonable risk exists, EPA has no duty—indeed, no authority—to act.

While EPA has wisely jettisoned its unfounded assumptions about the universal use of PPE, it has nevertheless reserved for itself an unrestricted right to consider some quantum of "reasonably available information" regarding PPE use at the risk-evaluation phase. Even if based on empirical data, this reliance on a "nonrisk

[15] *See* note 12, *supra.*

factor" still violates TSCA, as Congress has declared it irrelevant to determining risk, and as the record demonstrates, it will predictably lead to continuing underestimation of the risk toxic chemicals pose to workers.

A comparison to OSHA practice is instructive. Much like EPA, whose risk-evaluation mandate requires it to determine that a chemical presents an "unreasonable risk" to health or the environment, OSHA must conclude that a hazard poses a "significant risk" to workers before it may regulate the hazard. *See Indus. Union Dep't v. Am. Petroleum Inst.,* 448 U.S. 607, 656 (1980) ("*Benzene*"). Since the *Benzene* decision, OSHA has quantified risks to workers in several cases; in none of these risk assessments has OSHA reduced the measured exposure to a chemical based on PPE use.

Instead, OSHA regulations reflect that "[r]espirators are protective equipment" used to limit worker exposures. *Sec'y of Labor v. Seward Ship's Drydock, Inc.,* 937 F.3d 1301, 1303 (9th Cir. 2019). Respirators and other PPE, along with engineering controls and work practices, have always been viewed as means of *managing*, not *measuring* the risks chemicals pose in the workplace. Indeed, respirators represent the lowest, least-favored rung on the hierarchy of controls.

As both NIOSH and OSHA explained in their comments to EPA, engineering controls eliminate or reduce exposures at the source; work practice controls require

performing work in a way that limits exposures, such as requiring workers to use clean rooms for part of the workday. When properly implemented, both of those control strategies reliably reduce potential exposures. PPE, on the other hand, does nothing to control the environment, and its effectiveness is dependent on a number of variables, including whether it is appropriate for the particular exposures, whether it fits the worker and is maintained properly, and whether workers are properly trained in its use—something OSHA noted is "rarely the case."[16] Accordingly, OSHA regulations permit reliance on respirators "to supplement engineering and administrative controls only when these controls cannot be feasibly implemented to reduce employee exposure to permissible levels."[17]

Courts have reviewed several OSHA health standards promulgated under section 6(b)(5) of the OSH Act, 29 U.S.C. § 655(b)(5). In none of these cases has OSHA taken respirator or other PPE use into account in determining whether workers face a "significant risk." All of these OSHA standards considered respirators to be the least-preferred means of controlling worker exposures to the

[16] OSHA Methylene Chloride Comments, AR Ex. 0215 Att. 6 at 6; *see also* NIOSH Methylene Chloride Comments, AR Ex. 0215 Att. 5 at 6-7.

[17] OSHA Comments on EPA's HBCD Risk Evaluation, AR Ex. 0215 Att. 3 at 1; *see also, e.g.,* 29 C.F.R. § 1910.134(a)(2) (OSHA's respirator standard); *id.* § 1910.1047(f)–(g) (OSHA's ethylene oxide standard) (requiring engineering and work practice controls to reduce exposures and permitting respirators to control exposures in limited circumstances).

limit OSHA sets, and this and other courts have consistently evaluated their role in controlling worker exposures as part of its analysis of technological feasibility, not as a factor in estimating risk. *See, e.g., United Steelworkers of Am. v. Marshall,* 647 F.2d 1189, 1269 (D.C. Cir. 1980) (every earlier OSHA standard has included a section entitled "means of compliance" incorporating a preference for engineering and work practice controls over respirators); *Am. Iron & Steel Inst. v. OSHA,* 182 F.3d 1261, 1267–68 (11th Cir. 1999) (OSHA has incorporated a preference for engineering and work practice controls over respirators as a means of complying with its standards since 1971).

EPA, in some instances, has recognized that PPE is a "nonrisk factor" the Agency cannot consider in evaluating risk. In the preamble to the Revised Framework Rule, EPA explained it was abandoning its prior practice of assuming PPE use, pointing out that "TSCA risk evaluations are subject to statutory science standards, an explicit requirement to consider risks to potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk factors when determining whether a chemical presents an unreasonable risk that warrants regulatory actions." Revised Framework Rule, 89 Fed. Reg. at 37037. Accordingly, because "by law, [it] cannot consider costs or other non-risk factors" during risk evaluation, the Agency stated that it "does not take into account any existing occupational exposure controls" in deriving its "risk-based occupational

exposure value[s]." *Id.* at 37040. "However, when proposing any regulatory limit during the risk management phase, EPA may consider costs and other non-risk factors, such as . . . existing occupational exposure control approaches and technologies." *Id.*

In addition to acknowledging the statutory limit on its ability to consider PPE during risk evaluation, EPA has also pointed to practical reasons for refusing to do so. For example, EPA noted in the preamble to its proposed risk management rule for 1-bromopropane that while it may be presented with evidence of employer "best practices" during risk evaluation, "the Agency cannot assume that all facilities across all uses of the chemical substances will have adopted these practices for the purposes of making the TSCA risk determination," and that the Agency instead uses industry practices that "are clearly articulated to the Agency to help inform risk management decisions." EPA, NPRM, "1-Bromopropane (1-BP); Regulation Under the Toxic Substances Control Act (TSCA)," 89 Fed. Reg. 65066, 65072 (Aug. 8, 2024).

Similarly, in explaining its proposed risk management rule for n-Methylpyrrolidone (NMP), EPA noted that because it is not reasonable to assume that all facilities would have adopted the same controls, in determining unreasonable risk "it is appropriate to evaluate the levels of risk present in scenarios where no mitigation measures are assumed to be in place," while information regarding "different levels of mitigation" employed by industry "could be used during risk

management to tailor risk mitigation appropriately to address any unreasonable risk identified.....” EPA, NPRM, “n-Methylpyrrolidone (NMP); Regulation Under the Toxic Substances Control Act (TSCA),” 89 Fed. Reg. 51134, 51141 (June 14, 2024).

Despite all this, the Revised Framework Rule leaves EPA the discretion to “take information about PPE use “into account in the exposure assessment.” *Id.* at 37037. [18] Because—as EPA has recognized—TSCA’s plain language and Congress’ clear intent prohibit it from considering PPE during the risk evaluation phase of EPA’s two-step rulemaking process, the provision granting the Agency discretion to do so is invalid.

II. EPA’s Consideration of PPE as Part of Risk Evaluation Is Inconsistent with the Best Available Science.

TSCA directs EPA, both in evaluating risk and devising risk management rules, to use “methods, protocols [and] methodologies . . . in a manner consistent with the best available science.” 15 U.S.C. § 2625(h). Any consideration of

[18] The “exposure assessment” is one component of the risk evaluation process. *See* 40 C.F.R. § 702.39(d). *See, e.g..,* EPA, NPRM, “1-Bromopropane (1–BP); Regulation Under the Toxic Substances Control Act (TSCA),” 89 Fed. Reg. 65066, 65071 (Aug. 8, 2024) (noting that while in making its risk determination, “EPA believes it is appropriate to evaluate the levels of risk present in scenarios where no mitigation measures are assumed to be in place,” exposure estimates may reflect mitigation measures when they are “based on monitoring data at facilities that have existing engineering controls in place”). But PPE does not control the level of exposures in the workplace, and as discussed in the next section, its effect on exposures cannot be accurately measured.

respirator use during risk evaluation would run counter to well-settled industrial hygiene principles, and thus violate this mandate.

This is so because the effect of PPE use cannot be measured. Sampling devices cannot be attached inside a respirator's face piece because doing so would break the face piece's seal, which is critical to the respirator's effectiveness. Every comprehensive OSHA health standard defines employee exposure as the monitored level of a chemical in an employee's breathing zone, *without regard to respirator use*.[19] Accordingly, as OSHA has advised EPA, when it sets out to determine whether, as a threshold to regulating, the chemical poses a "significant risk," *Benzene,* 448 U.S. at 640, it "does not evaluate respirator impact in an initial characterization of risk."[20] Indeed, we are unaware of any occupational risk evaluation relied upon by a Federal agency that has reduced worker exposures by the protection factor assigned to a respirator—regardless of any "reasonably available information" about the prevalence of respirator use.

In addition to the technological impossibility of measuring the effect of PPE use in a factory setting, OSHA has consistently found respirators to be unreliable as

[19] *See, e.g.,* 29 C.F.R. § 1910.1052(b) (methylene chloride); *id.* § 1910.1001(b) (asbestos); *id*. § 1910.1025(d)(1)(i) (lead); *id*. § 1910.1048(b) (formaldehyde).

[20] OSHA Methylene Chloride Comments, AR Ex. 0215 Att. 6 at 6.

protection against harmful chemicals. Time and time again, OSHA has warned that respirators are "uncomfortable to wear, cumbersome to use, and interfere with communication in the workplace, which can often be critical to maintaining safety and health."[21] Courts have upheld OSHA's findings that respirators are "woefully inadequate" to protect workers due to "problems with adequate facial fit, increased heat stress, reduced vision, increased breathing resistance, speech limitation, limited mobility, and excess weight." *ASARCO, Inc. v. OSHA*, 746 F.2d 483, 496 n.27, 497 (9th Cir. 1984).[22] Thus, even if EPA receives information that respirators and other PPE are being used, there is no way for the Agency reliably to assess its overall effect on employee exposure.

For all these reasons, NIOSH advised EPA, in commenting on its initial methylene chloride risk evaluation, that "[i]n occupational risk assessment, risks

---

[21] OSHA Methylene Chloride Rule, 62 Fed. Reg. at 1583. *See also* OSHA, "Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite," 51 Fed. Reg. 22612, 22693 (June 20, 1986) (describing the limits of respirator use); OSHA, "Occupational Exposure to Respirable Silica," 81 Fed. Reg. 16286, 16293 (Mar. 25, 2016) (describing how OSHA health standards generally rely on the hierarchy of controls and limit respirator use).

[22] *See also AFL-CIO v. Marshall,* 617 F.2d 636, 653 n.80 (D.C. Cir. 1979), *aff'd sub nom. Am. Textile Mfrs. Inst. v. Donovan,* 452 U.S. 490 (1981) (affirming OSHA's reliance on engineering and work practice controls over respirators); *Pub. Citizen Health Rsch. Grp. v. U.S. Dep't of Lab.*, 557 F.3d 165, 179 (3rd Cir. 2009) (discussing why respirators are strongly disfavored).

should be calculated without regard for respiratory protection."[23] OSHA made the same point, telling EPA that OSHA does not evaluate respirator impact in an initial characterization of risk.[24] In continuing to look to PPE use as a factor in carrying out its statutory duty to evaluate risk without regard to nonrisk factors, EPA is disregarding the "best available science" as articulated by the most authoritative Federal agencies. This provision of the Revised Framework Rule must therefore be set aside as arbitrary and inconsistent with TSCA.

III. EPA's Consideration of PPE is Based on Misunderstandings of Employer Obligations under the Occupational Safety and Health Act.

In explaining why, in conducting its risk evaluations, it may consider evidence that some workers may be "exposed due to the absence or ineffective use of personal protective equipment," EPA stated that:

> [W]orkers may be highly exposed because they are not covered by [OSHA] standards, their employers are out of compliance with OSHA standards, the PPE is not sufficient to address the risk from the chemical, or their PPE does not fit or function properly.

Revised Framework Rule, 89 Fed. Reg. at 37037. These statements suggest that EPA understands OSHA regulations to impose some universal duty to provide PPE when workers are exposed to a hazardous chemical at *any* exposure level and that

[23] NIOSH Methylene Chloride Comments, AR Ex. 0215 Att. 4 at 3.

[24] OSHA Methylene Choride Comments, AR Ex. 0215 Att. 3 at 5.

risk results only when PPE is not provided or is used improperly. EPA has never identified which OSHA standards impose such a duty because no OSHA standard does so.

When OSHA issues a standard to protect against chemical exposures, it sets a permissible exposure limit ("PEL"), based not only on the agency's assessment of risk, but on considerations of technological and economic feasibility. *Am. Textile Mfrs. Inst., Inc. v. Donovan,* 452 U.S. 490, 509 (1981); 29 U.S.C. § 655(b)(5) (OSHA health standards must "assure[], to the extent feasible, . . . that no employee will suffer material impairment of health"). Employers are then required to comply with the PEL by following the hierarchy of controls, which—as explained earlier—prioritizes elimination, substitution and engineering and work practice controls that eliminate or minimize workplace exposures, permitting employers to resort to PPE only when the more favored options prove inadequate to bring exposures to the PEL. *See, e.g., Steelworkers v. Marshall,* 647 F.2d at 1271.

The OSH Act requires employers to comply with OSHA standards, but not to exceed them.[25] OSHA standards therefore do not require employers to implement

[25] 29 U.S.C § 654(a)(2) (employers "shall comply with [OSHA's] occupational safety and health standards"); *see also* OSHA Methylene Chloride Rule, 62 Fed. Reg. at 1581 (requiring the use of respirators "only if occupational exposures [to methylene chloride] . . . are likely to exceed the . . . PEL"); *Seward Ship's Drydock,* 937 F.3d at 1306 (interpreting OSHA's respirator standard, 29 C.F.R. § 1910.134, as requiring protection only when exposures exceed permissible levels).

any controls—PPE or otherwise—to bring exposures *below* the PEL. As OSHA informed EPA, OSHA air contaminant standards require employers to implement control measures to "prevent employee exposure to air contaminants from exceeding the prescribed limits" in those standards."[26]

Where no OSHA standard exists, the statute's "general duty clause" requires employers to provide a workplace free from "recognized hazards."[27] In the absence of a permissible exposure limit, however, OSHA has rarely—if ever—used the general duty clause to require employers to control exposures to a specific level.[28]

---

[26] OSHA HBCD Comments, AR Ex. 0215 Att. 3 at 1. *See also,* OSHA Methylene Chloride Comments, AR Ex. 0215 Att. 6 at 1 ("It is important to note that respirators are required only when concentrations will exceed the [OSHA] PEL.")

[27] 29 U.S.C. § 654(a)(1) (employers must provide each employee "employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm"). The general duty clause does not set across-the-board requirements that employers must adopt. *See* EPA, NPRM, "Carbon Tetrachloride (CTC); Regulation Under the Toxic Substances Control Act," 88 Fed. Reg. 49180, 49184 (July 28, 2023). EPA has correctly identified many obstacles OSHA would face if it tried to rely on the general duty clause to force reductions in chemical exposures. EPA, NPRM, "Methylene Chloride: Regulation under the Toxic Substances Control Act (TSCA))," 88 Fed. Reg. 28284, 28288 (May 3, 2023).

[28] Under limited circumstances, OSHA has the authority to use the general duty clause to require employers to control exposures below an established PEL. See *Int'l Union, UAW v. Gen. Dynamics Land Sys. Div.*, 815 F.2d 1570 (D.C. Cir. 1987). To do so, however, OSHA must establish actual employer knowledge that the standard was inadequate to protect employees from death or serious physical harm. *Id.; see also* OSHA Field Operations Manual, Chapter 4, Section II.D.2 (2022), *available at* https://www.osha.gov/fom/chapter-4#general-duty

As California's OSHA program informed EPA in commenting on the Agency's assumptions about PPE use in its risk evaluation for NMP:

> When assuming workers use respirators, EPA failed to take into account that OSHA has no PEL to protect workers against the adverse health effects of NMP. As a result, there is no express requirement in federal law for employers to establish a respiratory protection program to reduce worker exposures to NMP to below a certain level or to provide respirators.
>
> Employers are highly unlikely to institute a respiratory protection program without an express requirement, due to the effort necessary to establish such a program.

Comment of California Department of Public Health/Occupational Health Branch, AR Ex. 0206.

Nor does OSHA's Respiratory Protection Standard impose a duty on employers to provide respirators at all levels of exposure to a hazardous chemical. That standard requires employers, "[w]hen effective engineering controls are not feasible," to provide a respirator "to each employee when such equipment is necessary to protect the health of such employee." 29 C.F.R. § 1910.134(a)(1)–(2).

EPA's apparent assumption that the respirator standard requires employers to provide effective protection to the levels EPA considers as posing unreasonable risk is incorrect.[29] When OSHA initially proposed its respiratory protection standard,

[29] OSHA's PELs are all likely to be much higher than levels at which EPA determines chemicals to pose unreasonable risks, since—unlike EPA—OSHA

the standard would have required employers to implement the hierarchy of controls, even if OSHA had not adopted a PEL for a chemical, if exposures exceeded either a NIOSH Recommended Exposure Limit (REL), an American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) or "*any exposure level based on available scientific information*, including Material Safety Data Sheets." OSHA, "Respiratory Protection," 63 Fed. Reg. 1152, 1183 (Jan. 8, 1998) (emphasis added). Had OSHA adopted this proposal, an EPA determination of unreasonable risk might have triggered a duty to comply with OSHA's respiratory protection standard.

But OSHA did not adopt the proposal and made clear that the standard "does not identify the ACGIH TLVs or the NIOSH RELs as references that would trigger required respirator use." *Id.* Since OSHA considered and rejected an approach that would have triggered the respirator standard based on "available scientific information," such as an EPA finding of unreasonable risk, EPA's assumption that

---

standards are restricted by feasibility considerations and, as EPA acknowledges, most are sorely outdated. In fact, EPA has recognized that there is a gulf between the level at which OSHA regulates exposures and level at which EPA must regulate under TSCA. *See*, *e.g.,* EPA, NPRM, "Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA)," 88 Fed. Reg. 74712, 74719 (Oct. 31, 2023) (EPA believes that OSHA chemical standards would in general be unlikely to address unreasonable risk within the meaning of TSCA).

the respirator standard *might* apply is plainly wrong—and OSHA has told EPA as much.[30]

In short, to the extent EPA is proceeding from an assumption that OSHA standards impose an obligation on employers to provide respirators to protect their employees from *all* levels of exposure to a toxic chemical, and harmful exposures will only occur "when workers are exposed due to the absence or ineffective use of" PPE, those assumptions lack evidentiary basis, and are, in fact, simply incorrect.

IV. PPE Use May Be Considered During Risk Management.

We have no doubt that some employers voluntarily provide respirators to workers at exposure levels below OSHA PELs. While these efforts are commendable, such policies by individual employers do not protect all workers. Moreover, they are voluntary, not mandatory. EPA has repeatedly noted that "it does not question public comments" indicating some employers have reduced exposures to levels below the OSHA PEL, but that observation is meaningless from either a risk evaluation or regulatory perspective. EPA cannot meet the requirements of TSCA section 6—to evaluate hazard and exposure —by pointing to unenforceable, voluntary efforts by some, but not all, employers. *Cf. Steelworkers v. Marshall,* 647 F.2d at 1265 n.106 (recognizing that while many employers do more than necessary

[30] OSHA HBCD Comments, AR Ex. 0215 Att. 3 at 1.

to protect workers, mandatory requirements prevent employers who do not from gaining a competitive advantage).

Labor Petitioners believe that EPA can, and should, use "reasonably available information" about engineering and work practice controls, as well as documented PPE use, in making its risk *management* decisions. Data on employer practices can inform EPA decisions about what technology is available and what reductions in exposure the technology can feasibly accomplish. While EPA can reasonably point to "employer best practices" during risk *management* to show the efficacy of its proposed workplace chemical protection programs—and indeed, employers that are already voluntarily implementing effective controls should have little to do to comply with EPA's risk management rules—information on employer best practices should play no role in risk *evaluation*.

CONCLUSION

As we have detailed above, EPA's reservation of the right to consider PPE use in determining whether a toxic substance poses an unreasonable risk to workers violates TSCA's instruction that EPA make this determination without considering "nonrisk factors" and is inconsistent with the "best available science" and well-established public health principles. Furthermore, EPA's views about PPE use appear to rely on a misunderstanding of the requirements of OSHA standards. For all of these reasons, this Court should declare invalid the first sentence of 40 C.F.R.

§ 702.39(f)(2), the provision of the Revised Framework Rule that permits EPA to consider the effect of respirators or other PPE during risk evaluation and hold that EPA may only consider the role of PPE during risk-management rulemaking.

Respectfully submitted,

/s/Randy S. Rabinowitz
Randy S. Rabinowitz, Esq.
Victoria L. Bor, Esq.
Occupational Safety & Health Law Project, LLC
P.O. Box 3769
Washington, D.C. 20027
202/256-4080

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because the brief uses a monospaced typeface and contains 8201 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in 14-point typeface using Time New Roman font.

Dated: October 10, 2024
Washington, D.C.

_/s/ *Randy S. Rabinowitz*
Attorney for Petitioner, USW

CERTIFICATE OF SERVICE

I hereby certify that I e-filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system on October 10, 2024.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

Dated: October 10, 2024
Washington, D.C.

s/ *Randy S. Rabinowitz*
Attorney for Petitioner, USW

STATUTORY ADDENDUM

TOXIC SUBSTANCES CONTROL ACT

Section 3, § 2602 – Definitions

(12) The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

Section 6, § 2605. Prioritization, risk evaluation, and regulation of chemical substances and mixtures

(a) Scope of regulation

If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk:

(1) A requirement (A) prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement-

(A) prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use

or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6)

(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture

(A) to give notice of such determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture,

(B) to give public notice of such determination, and

(C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

(b) Risk evaluations

(1) Prioritization for risk evaluations

(A) Establishment of process

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

(B) Identification of priorities for risk evaluation

(i) High-priority substances

The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

(ii) Low-priority substances

The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk

factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

(C) Information request and review and proposed and final prioritization designation

The rulemaking required in subparagraph (A) shall ensure that the time required to make a priority designation of a chemical substance be no shorter than nine months and no longer than 1 year, and that the process for such designations includes-

(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided;

(ii) a requirement that the Administrator publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation; and

(iii) a process by which the Administrator may extend the deadline in clause (i) for up to three months in order to receive or evaluate information required to be submitted in accordance with section 2603(a)(2)(B) of this title, subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

(2) Initial risk evaluations and subsequent designations of high- and low-priority substances

(A) Initial risk evaluations

Not later than 180 days after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.

(B) Additional risk evaluations

Not later than three and one half years after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

(C) Continuing designations and risk evaluations

The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with this subsection at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

(D) Preference

In designating high-priority substances, the Administrator shall give preference to-

(i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and

(ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(E) Metals and metal compounds

In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(3) Initiation of risk evaluations; designations

(A) Risk evaluation initiation

Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

(B) Revision

The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

(C) Ongoing designations

The Administrator shall designate at least one high-priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

(4) Risk evaluation process and deadlines

(A) In general

The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

(B) Establishment of process

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

(C) Requirement

The Administrator shall conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B), for a chemical substance-

(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria

prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

(D) Scope

The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

(E) Limitation and criteria

(i) Percentage requirements

The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subparagraph (C), the number of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is-

(I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and

(II) not more than 50 percent.

(ii) Requested risk evaluations

Requests for risk evaluations under subparagraph (C)(ii) shall be subject to the payment of fees pursuant to section 2625(b) of this title, and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations.

(iii) Preference

In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions

imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

(iv) Exceptions

(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) shall not be subject to section 2617(b) of this title.

(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

(F) Requirements

In conducting a risk evaluation under this subsection, the Administrator shall-

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

(v) describe the weight of the scientific evidence for the identified hazard and exposure.

(G) Deadlines

The Administrator-

(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates the risk evaluation under subparagraph (C); and

(ii) may extend the deadline for a risk evaluation for not more than 6 months.

(H) Notice and comment

The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.

(c) Promulgation of subsection (a) rules

(1) Deadlines

If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator-

(A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

(C) may extend the deadlines under this paragraph for not more than 2 years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed 2 years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the

Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

(2) Requirements for rule

(A) Statement of effects

In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to-

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, including consideration of-

(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

(B) Selecting requirements

In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

(C) Consideration of alternatives

Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

(D) Replacement parts

(i) In general

The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

(ii) Definitions

In this subparagraph-

(I) the term "complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

(II) the term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

(E) Articles

In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

(3) Procedures

When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5 (without regard to any reference in such section to sections 556 and 557 of such title), and shall also-

(A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule;

(B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;

(C) promulgate a final rule based on the matter in the rulemaking record; and

(D) make and publish with the rule the determination described in subsection (a).

(d) Effective date

(1) In general.-In any rule under subsection (a), the Administrator shall-

(A) specify the date on which it shall take effect, which date shall be as soon as practicable;

(B) except as provided in subparagraphs (C) and (D), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);

(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and

(E) provide for a reasonable transition period.

(2) Variability.-As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.

(3)(A) The Administrator may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 2605(a) of this title or until the Administrator revokes such proposed rule, in accordance with subparagraph (B), if-

(i) the Administrator determines that-

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date without consideration of costs or other non-risk factors; and

(II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 2606 of this title granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action in accordance with subsection (c), and either promulgate such rule (as proposed or with modifications) or revoke it.

[subsections (e), Polychlorinated biphenyls; (f) Mercury; (g) Exemptions; and **(h) Chemicals that are persistent, bioaccumulative, and toxic omitted]**

(i) Final agency action

Under this section and subject to section 2617 of this title-

(1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order; and

(2) a final rule promulgated under subsection (a), including the associated determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

(j) Definition

For the purposes of this chapter, the term "requirement" as used in this section shall not displace statutory or common law.

****

Section 26, 15 U.S.C. § 2625 – Administration

(h) Scientific standards.

In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

OCCUPATIONAL SAFETY AND HEALTH ACT

Section 5(a), 29 U.S.C. § 655(a) – Duties of Employers

(a) Each employer—

(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) shall comply with occupational safety and health standards promulgated under this chapter.

Section 6(b)(5), 29 U.S.C. § 655(b)(5) –

(b) Procedure for promulgation, modification, or revocation of standards

The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

***

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most

adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.